REMARKS

The amendments in the previous case resolve all outstanding issues except the single rejection under § 103(a) based on the combination of seven references: Cajigas, taken with Gonzalez Barberan, Levy, Prescott et al., Fletcher et al. and Merck further taken with Jolly and Friend et al.

Applicant recognizes that the Examiner can select a given parameter or element of the pending claims and then locate the corresponding element somewhere in the references. However, the proper exercise is an analysis of whether the combination of references properly establishes a prima facie case that makes the claimed combination obvious as a whole.

It is also recognized that Cajigas is a dry combination of certain yogurt components and that Levy is also a dry formulation. In the context of the § 103 analysis, it is <u>assumed</u>, as is disclosed in applicant's specification, that the prior art teaches a dry composition of Lactobacillus, and some other elements of the claimed composition. The pertinent question is whether one of ordinary skill in the art would look to references such as Jolly and Friend, which only disclose wet compositions, for a solution to the problem of decreasing bacterial counts over a lengthy storage time. As noted previously, Jolly (USP 4,107,334), uses water or a water-based liquid in every example of the modified protein described therein.

Similarly, the Friend reference discusses the beneficial properties of *Lactobacillus* cultures, in general, but discloses only the administration of *Lactobacillus* in wet cultured dairy products, specifically yogurt and milk.

OC-129098.1 DOCSOC1:139541.1 708005-8 K2M The question thus becomes: can one find in the references both a combination that establishes a <u>prima facie</u> case under § 103, given that the requisition motivation to combine the references must exist, and the combination must not violate the teachings of the references.

The conceptual framework for the § 103 analysis presupposes that one of ordinary skill knows the prior art that is in the present record and that the hypothetical person is interested in overcoming the same problem faced by the inventors here, namely, the shelf-life limitation caused by decreasing bacterial counts. Applicant argues that one of ordinary skill in the art, considering this problem and knowing of the dry Lactobacillus formulations, would not look to components only found in other wet formulations to solve a problem existing in dry storage. The Examiner's citation to the several references disclosing individual components of the pending claims does not establish a proper 35 U.S.C. § 103 rejection of the claimed invention, which must be considered "as a whole," because the rationale for making the combination of these references is not present and cannot reasonably be supposed to exist because of the wet/dry conundrum. Also, the Examiner should consider, as has been previously noted, that the modification to Jolly and Friend necessary for a dry composition as claimed would render the references unsuitable for their intended purpose. Any combination that includes Jolly (USP 4,107,334) and Friend necessarily yields a wet composition. Because the combination of references used in the § 103 rejection necessarily yield a wet composition, a feature directly contrary to the pending claims, this fact indicates that the proposed combination must be permissibly altered to attempt to make out a § 103 rejection.

The Examiner's position on the addition of a protein <u>concentrate</u> to a bacteria and yeast composition offers absolutely no rationale for one of ordinary skill to actually make the combination. If the standard were simply that any component could be added to a composition "for

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their known benefit," then any combination of beneficial compounds would be unpatentable. In fact, the failure of the references as a whole to teach the dry admixture, the specific concentrations, and the protein concentrate component shows that the combination as a whole would not have been made by one of ordinary skill in the art.

Applicants have previously addressed the PTO's error in reliance on <u>In re Sussman</u>, 1943 C.D. 518, and the forbidden concept of synergism. Applicants are not, as yet, arguing "unexpected results" to rebut a <u>prima facie</u> case under § 103. Applicants simply content that the PTO has not established a proper § 103 rejection based on the combination of the references.

For this reason, Applicants submit that the pending claims are in a position to be allowed.

Respectfully submitted,

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